K052916

NOV - 9 2005

SUMMARY OF SAFETY AND EFFECTIVENESS

1. Device Name:	Magnetic Resonance Imaging Accessory
2. Proprietary Name:	3.0T 16 Channel Brain-Spine () Array Coil
3. Classification:	Class II
4. Establishment Registration #:	1529041
5. Manufacture Facility Location:	USA Instruments, Inc. 1515 Danner Drive Aurora, Ohio 44202, USA Telephone: 330-562-1000; Fax: 330-562-1422.
6. Performance Standard:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
7. Intended Use:	The 3.0T 16 Channel Brain-Spine (NV) Array Coil is a receive-only phased array RF coil, used for obtaining diagnostic images of the brain, cervical spine, soft tissues and vasculature of the head, neck and upper chest, thorasic and lumbar spine in Magnetic Resonance Imaging Systems. The 3.0T 16 Channel Brain-Spine (NV) Array Coil is designed for use with the 3.0T MRI systems manufactured by GE Medical Systems.
8. Device Description:	The 3.0T 16 Channel Brain Spine () Array Coil is a multi-element phased array receive only coil. The coil has a rigid enclosure. The open, patient friendly design eases patient handling and positioning and maximizes patient comfort. The coil elements and accessory electronics are enclosed in a rigid plastic housing, which is fire rated and has a high impact and tensile strength.
9. Marketed Device:	3.0T Brain / Spine Array
10. Comparison with Predicate:	The 3.0T Brain / Spine Array is a modification of the existing cleared USA Instruments 3.OT 8 Channel Neurovascular Array coil (K032618) with the main difference being the physically integration of the antenna and shape of the Premier III Linear Phased Array CTL Spine Coil with the antenna and shape of the Millennium 9000 Phase Array Neurovascular coil. The integration increases the number of receive channels to 16 to make it compatible with the GE Healthcare Signa Excite 3.0T Magnetic Resonance Scanners. Both coils included spine

	imaging in their indications, but this modification improves user workflow by allowing more comprehensive patient coverage with a single coil.
11. Summary of Studies:	Testing was performed to demonstrate that the design modifications to the 3.0T Brain / Spine Array meet predetermined acceptance criteria.

Conclusion:

It is the opinion of USA Instruments that the 3.0T Brain / Spine Array is substantially equivalent to the USA Instruments 3.0T 8 Channel Neurovascular Array coil (K032618) Usage of the USA Instruments 3.0T Brain / Spine Array does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2005

Mr. Robert B. Smith
Quality Assurance/
Regulatory Affairs Manager
USA Instruments
1515 Danner Drive
AURORA OH 44202

Re.: K052916
Trade/Device Name: 3.0T 16 Channel Brain-Spine (Neurovascular) Array Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: October 12, 2005
Received: October 17, 2005

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registrations, listing of devices, good manufacturing practice, labeling and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advices that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of he Act or any Federal statues and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K052916

Device Name: **3.0 T 16-Channel Brain-Spine (Neurovascular) Array Coil**

Indications for Use

The 3.0T Brain / Spine Array Coil is designed for use with the Excite 3.0T MRI system manufactured by GE Healthcare. The coil is for imaging of the brain, cervical spine, soft tissues and vasculature of the head, neck, upper chest, thoracic and lumbar spine. The nucleus excited is hydrogen.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052916